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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,031	03/07/2006	Maria Jose Alonso Fernandez	4258-117	6063

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INTELLECTUAL PROPERTY / TECHNOLOGY LAW
PO BOX 14329
RESEARCH TRIANGLE PARK, NC 27709

EXAMINER	
WESTERBERG, NISSA M	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
03/27/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,031	FERNANDEZ ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 - 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 - 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/14/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112 2nd Paragraph

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1 – 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Step a) in claim 1 contains the phrase "the weight ratio of both polymers being between 1:0.1 and 1:3". Because of the presence of the word "both", it is unclear whether weight ratio claimed is the ratio of the biodegradable polymer to the polyoxyethylene-derived block copolymer or the weight ratio of the total amount of the two polymers to some other quantity (such as the mass of the organic solvent). For the purposes of applying art below, the claim has been interpreted as being a weight ratio of the biodegradable polymer to the polyoxyethylene-derived block copolymer.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 3, 6, 7, 10 – 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Grandfils et al. (US Patent 5,962,566, entire document).

As to claims 1, 3, 6, 7, 10 and 11, in example 1 (col 5, ln 17 onward), the poloxamer PLURONIC® F68 and lactide-co-glycolide polymer (PLGA, exemplified on p 9, ln 5 of the instant application as a biodegradable polymer that is a member of the polyester family) are dissolved in an organic solvent (col 5, ln 20 – 24). The weight ratio of these two components was 1:1 (col 5, ln 20 – 21). The average molecular weight of PLURONIC® F68 is 8400 Daltons (see product information sheet for PLURONIC® F68). The active ingredient with therapeutic properties, somatotropin, is added to the organic solution before being added to the polar (water) solution (col 5, ln 31 – 33). The organic solution was dispersed using a roto-stator equipment (mixer) with the polar phase. The organic solvent was removed by diafiltration (col 5,ln 43 – 45). This filtration step also results in the isolation of the nanoparticles. The mean size of the PLGA/PLURONIC® F68 blend particles was 100 to 140 nm (col 6, ln 16 – 17).

As to claim 2, the nanoparticles can be freeze-dried (lyophilized; col 5, ln 48 – 49).

Claims 12 – 17 are product-by-process claims. The nanoparticles of claims 12 and 13 are anticipated by Grandfils et al. as the nanoparticles are made by the same process.

As to claims 14 – 17, which relate to a composition, a pharmaceutical composition or a cosmetic composition containing the nanoparticles produced by such a

process, Grandfils et al. discloses that a suspension of the particles was prepared (col 5, ln 45 – 47), thus meeting the limitation of a composition comprising the nanoparticles. The release rate of the protein (a molecule with therapeutic properties or a pharmaceutical) was determined so a pharmaceutical composition was also prepared.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 4, 8, 9, and 14 – 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grandfils et al. in view of Kreitz et al. (PGPub 2004/0220081).

As discussed above Grandfils et al. describes a process of making nanoparticles comprising dissolving PLGA, a biocompatible polymer, and a poloxamer in an organic phase, mixing the organic phase with the active ingredient with a polar phase to produce isolated nanoparticles containing an active ingredient.

Grandfils et al. does not disclose the use of polyanhydrides or poloxamines to make nanoparticles.

Kreitz et al. discloses nanoparticles with biologically active ingredients that exhibit enhanced dissolution and/or uptake rates (paragraph [0001]). The bioerodible polymers used to make such nanoparticles include polyesters such as poly(lactic acid), poly(glycolic) acid and poly(lactide-co-glycolide) polymers and polyanhydrides (paragraph [0041]). The polyoxyethylene-derived block copolymers of poloxamers and polyamines are both taught as dispersants (paragraph [0051]). The exemplified poloxamine, TETRONIC® 908 has an average molecule weight of 25,000 Daltons (see product information sheet for TETRONIC® 908). The nanoparticles can be used alone

or added into tablets, capsules or other pharmaceutical dosage forms (paragraph [0033]), resulting in pharmaceutical composition comprising nanoparticles.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to replace the PLGA polymer and poloxamer in the method and nanoparticles taught by Grandfils et al. with polyanhydride and poloxamine because the components are taught as functional equivalents by Kreitz et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8 a.m. - 4 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW